JUN 12 2003

K031264

5. 510 (k) Summary

Submitter of 510(k): Wieland Dental + Technik GmbH & Co. KG
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Date of Summary: 2003-04-10

Trade name: Porta PressOver

Classification name: Alloy, gold based, for clinical use
Product code: EJT
C.D.R section: 872.3060
Classification: Class II

Legally marketed equivalent device: Pontor 4CF

510(k) number: K911541

Device description

Porta PressOver is a gold-silver-palladium alloy (type 3) with high contents of noble metals (76,5%) intended for dental technicians to fabricate dental restorations.

It has an indication for use, which ranges from inlays/onlays and single crowns up to short span bridges with two pontics. In addition, it can be used for telescopic and milling work.

Porta PressOver can be utilized as a conventional casting alloy as well as a ceramic alloy, which has to be veneered by the Pressover-Technique with IMAGINE® h.e. Press Ceramic.

Porta PressOver is highly corrosion resistant and has an excellent biocompatibility. It meets all relevant essential requirements of the European directive 93/42/ECC concerning medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2003

Gerhard Polzer, Ph.D.
Director, Regulatory Affairs
Wieland Dental + Technik GmbH & Co. KG
Schwenninger Strasse 13
D-75179 Pforzheim
GERMANY

Re: K031264
Trade/Device Name: Porta PressOver
Regulation Number: 21 CFR 872.3060
Regulation Name: Gold Based Alloys and Precious Metal Alloys for Clinical Use
Regulatory Class: II
Product Codes: EJT
Dated: April 17, 2003
Received: April 22, 2003

Dear Dr. Polzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K031264

DEVICE NAME: Porta PressOver

INDICATIONS FOR USE:

Porta PressOver is a gold-silver-palladium alloy that can be used by dental technicians to fabricate dental appliances for patients.

It is intended for manufacturing

- Inlays/Onlays
- Crowns
- Short span bridges

and can be used for

- Telescopic and milling work

Porta PressOver can be utilized as a conventional casting alloy, in which it can be veneered with dental composites, as well as a ceramic alloy, which has to be veneered (pressed over) by the IMAGINE h.e. Press ceramic of Wieland Dental + Technik GmbH & Co. KG.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

Kai Mulay for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control. Dental Devices

510(k) Number K031264